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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,795	09/05/2001	Gunther Berndl	49727	4232

7590 12/18/2001

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EXAMINER

GOLLAMUDI, SHARMILA S

ART UNIT PAPER NUMBER

1616

DATE MAILED: 12/18/2001

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/914,795	BERNDL ET AL.
	Examiner Sharmila S. Gollamudi	Art Unit 1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 01 September 2001.

2a) This action is FINAL.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-9 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-9 is/are rejected.

7) Claim(s) 1 is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1.  Certified copies of the priority documents have been received.

2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1)  Notice of References Cited (PTO-892)

2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)  Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.

4)  Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.

5)  Notice of Informal Patent Application (PTO-152)

6)  Other: \_\_\_\_\_

### **DETAILED ACTION**

Claims 1-9 are included in the prosecution of this application.

Preliminary Amendments are acknowledged.

The references cited in the Search Report have been considered, but will not be listed on any patent resulting from this application because they were not provided on a separate list in compliance with 37 CFR 1.98(a)(1). In order to have the references printed on such resulting patent, a separate listing, preferably on a PTO-1449 form, must be filed within the set period for reply to this Office action.

#### ***Claim Objections***

Claim 1 is objected to because of the following informalities: Proper Markush language is "selected from the group consisting of A, B, and C. Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over**

**Nagafuzi et al (5290569) by itself or in view of Klimesh et al (4880585).**

Nagafuzi et al discloses a coated composition containing an active agent, cyclodextrin, a polymeric binder, and excipient (Example 1 and 3). Nagafuzi et al teach the amount of both cyclodextrin and active in instant amount (Example 1). The reference teaches the process of heating the composition below 220 degrees Celsius without a solvent (col. 1, lines 49-55). Nagafuzi et al discloses that the coated granules can be compressed into tablets (col. 1, lines 18-25).

Nagafuzi et al does not teach the process of tabletting or the use of a molding calendar with opposite rollers.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to manipulate the conditions of Nagafuzi et al and use any method of tabletting known to one of ordinary skill in the art at the time the invention was made. One would be motivated to do so since Nagafuzi et al provide the general guidance to make active substance sensitive to a solvent composition and suggests compressing the coated granules to make a tablet.

Klimesh et al teaches a method of continuous tabletting using a molding calendar with opposite rollers (col. 1, lines 16-27). The reference teaches the use of instant polymeric binder and instant temperature (col. 2, lines 40-68). The advantage of the process is it makes premixing unnecessary (col. 1, lines 28-34).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Nagafuzi et al and Klimesh et al. One would be motivated to do so since Klimesh et al teaches the advantages using mold calendaring to make tablets of a pharmaceutical mixture such as Nagafuzi et al.

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**Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/18839.**

WO 97/18839 teaches a tablet containing cyclodextrin (67%), an active (33%), and crospovidone (17%) (Note example 5). The reference teaches various ratios of the active to cyclodextrin (pg. 11, lines 1-5). Further, WO 97/18839 discloses that different temperatures may be applied and discloses the method of ascertaining the required temperature (pg. 10, lines 29-35). The reference also teaches a method of tableting (pg 4 and 5, line 30 to line 20).

The reference does not teach the active agent in the amount of 30%, instant ratio, or counter rotating rolls.

It is deemed obvious to one of ordinary skill in the art at the time the invention was made to manipulate the conditions set forth by WO 97/18839 to obtain the best possible results. One would be motivated to do since WO 97/18839 provides a general guidance to make the composition and tablet it. Further motivation to do so being that the ratio of the active to cyclodextrin depends on the type of active and cyclodextrin used and the reference discloses the method of ascertaining the temperature.

In the absence of showing criticality of the counter rotating rolls and the process of tableting being known in the art at the time the invention was made, it is deemed obvious to one of ordinary skill in the art at the time the invention was made to use co rotating rolls or counter rotating rolls in the process of tableting.

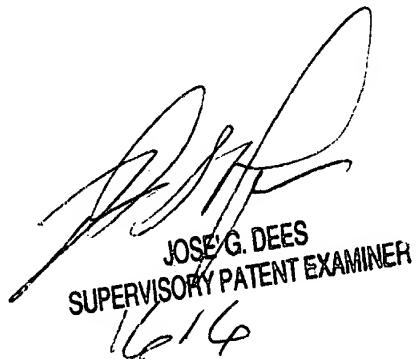
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Any inquiry concerning this communication from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is (703) 305-2147. The examiner can be normally reached M-F from 7:30 am to 4:15pm.

If attempts to reach the examiner by the telephone are unsuccessful, the examiner's supervisor, Jose Dees, can be reached at (703) 308-4628. The fax number for this organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist, whose telephone number is (703) 308-1235.

SSG



JOSE G. DEES  
SUPERVISORY PATENT EXAMINER  
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